Amendments to the Drawings:

In response to the Examiner's objection to the drawings, submitted herewith is a new Fig. 9, which illustrates the basic described features of an apparatus that may be employed in the present claimed process. As Fig. 9 merely illustrates apparatus in accordance with basic described features, no new matter has been added.

REMARKS

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Examiner asserts that the specification fails to indicate how an impeller can be mounted in a particle formation vessel so as to impart both a highly agitated zone within one impeller diameter and also a bulk mixing zone at greater distances from the impeller, and also how feed stream introduction ports can be configured and located relative to the impeller and impeller diameters, or structural relationships among introduction ports, mixing chamber and impeller agitator. The Examiner further alleges that the 3 patents referenced by the specification at pages 10-12 in this regard only appear to give a single zone of mixing in impeller-containing vessels, and that there are no drawings in the instant application to provide clarity to the claimed combination of mixing zones. This rejection is respectfully traversed.

Contrary to the Examiner's assertions, the specification does in fact explains how an impeller can be employed so as to impart both a highly agitated zone within one impeller diameter and also a bulk mixing zone at greater distances from the impeller. See, e.g., the explanations in accordance with the present invention in the paragraphs beginning at page 9, line 5 (that effective meso and micromixing and resulting intimate contact of the feed stream components is enabled by introduction of the feed streams into the vessel within a distance of one impeller diameter from the surface of the impeller of the rotary agitator) and page 10, line 1 (that a significant fraction of the power provided for mixing is dissipated within the highly agitated zone within one impeller diameter). As it is clear that the energy is largely dissipated within one impeller diameter, it is clear that mixing in the remaining volume of the vessel occurs by bulk mixing (or "bulk circulation" or "macromixing"), such as further discussed in the paragraphs beginning at page 11, line 3 and page 11, line 21. Further, the concepts of mesomixing, micromixing and macromixing are in any event well known to one skilled in the art (such as discussed in the paragraph beginning at page 5, line 12 of the specification). The present invention is not directed towards new apparatus to achieve such types of mixing, but rather the application of known types of mixing apparatus (rotary agitators) in a new process which enables formation of particulate material of a desired substance at a desired small size. The specification clearly describes examples of such known type of mixing

apparatus that may be employed in the claimed process which enable both a relatively highly agitated turbulent flow zone located within a distance of one impeller diameter from the surface of the impeller of the rotary agitator, and a bulk mixing zone located at distances greater than one impeller diameter from the surface of the impeller a highly agitated zone (see, e.g., page 9, line 24 through page 12, line 26, and especially explanations with respect to energy dissipation and bulk circulation therein). The Examiner's further allegation that the 3 patents referenced by the specification at pages 10-12 in this regard only give a single zone of mixing in impeller-containing vessels is thus clearly not supported. Accordingly, there is no basis for the Examiner's that the specification fails to indicate how an impeller can be mounted in a particle formation vessel so as to impart both a highly agitated zone within one impeller diameter and also a bulk mixing zone at greater distances from the impeller.

Further, the specification also explains that such known types of mixing apparatus employ means for introducing feed streams from a remote source by conduits which terminate close to an adjacent inlet zone of the mixing device which is less than one impeller diameter from the surface of the mixer impeller (page 10, lines 21-24). While no drawings are provided to specifically illustrate such known types of mixing apparatus, this is not required as the claimed invention is not directed towards any specific novel apparatus, but rather to a process. Further, in any event, as stated at page 10, lines 1-2, the specific configurations of the rotary agitators which may be employed in the present invention may vary significantly. As the specific requirements of the claimed process are clearly delineated, and as apparatus which may be employed in the claimed invention is clearly known and adequately described, reconsideration of this rejection is respectfully urged.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

It appears the asserted basis for such rejection is the same as that set forth in the rejection based on the alleged lack of enablement, which arguments are addressed above. Further with respect to written description, the present claimed invention is clearly adequately supported by the original written description, as claim 1 essentially is set forth in the original summary of the invention at page 6, lines 5-30, with the added features of specifying that feed streams of the solution and of a supercritical fluid are introduced in a highly agitated turbulent flow zone, which feature is clearly supported at page 7, line 31, and that the particles of the desired substance precipitated in the particle formation vessel have a volume-weighted average diameter of less than 20 nanometers, which feature is clearly supported by Examples 4-8 as originally filed (and specifically, Example 6 which explicitly states a mean particle size of less than 20 nm). As the claimed subject matter accordingly is clearly supported by the written description as originally filed, and also clearly enable as explained above, reconsideration of this rejection is respectfully urged.

The drawings are objected to under 37 CFR 1.83(a) for failing to show every feature of the invention specified in the claims, the Examiner stating that the claimed impeller, impeller diameters and configuration relative to location of the 1st and 2nd stream introduction ports, and formation/configuration of different mixing zones relative to distance from the impeller surfaces and impeller diameters must be shown or the feature(s) canceled from the claims. It is believed that a drawing of such apparatus elements is not required for an understanding of the claimed process, as the claimed invention is not directed towards new apparatus *per se* and as the specific requirements of apparatus employed in the claimed process are clearly delineated. To advance prosecution, however, a new Fig. 9 is submitted herewith which illustrates the basic described features of an apparatus that may be employed in the present claimed process. As Fig. 9 merely illustrates apparatus in accordance with the basic described features, no new matter has been added. New paragraphs have been added at pages 7 and 9 of the specification, describing the new Fig. 9. Again, no new matter has been added.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saim et al patent 6,858,166 in view of Johnson et al PGPUBS Document US2004/0091546 and O'Conner et al PGPUBS Document US2006/0124783. This rejection is respectfully traversed.

The Examiner states that Saim et al disclose formation of micro or nano-particles by a process of admitting a supercritical fluid to a vessel, in which temperature and pressure are controlled (column 14, lines 21-45), agitating such vessel with a rotary agitator comprising an impeller of un-specified, given diameter relative to vessel diameter (column 14, line 63column 15, line 6), introducing a 1st feed stream comprising a solvent and desired, active substance through a 1st introduction port and introducing a 2nd feed stream comprising the supercritical fluid through introduction ports both approximately within the highly agitated zone of the mixer that may be an impeller (see especially figures 1 and 2 and column 18, lines 30-63). The Examiner further states that both a first feed stream including particle-forming components and solvent and a second feed stream containing supercritical fluid may be introduced proximate the agitated/highly agitated zone of the mixer (see column 12, lines 11-12 taken with lines 33-36 of column 12), and that particles are then precipitated within such vessel over a carrier bed.

The Examiner further states that O'Connor et al teaches to produce nanoparticles using solvents and supercritical fluids by use of conversion/mixing vessels that combine impeller mixers with other type stirrers, that have inlets for introducing solvents and other materials, and/or have a plurality of impeller mixers or impellers with differently functioning blades so as to create different mixing zones of different degrees of turbulence (referencing especially paragraph 33 and paragraphs 22-32 and 38-40). The Examiner states it would have been obvious to one of ordinary skill in the art to have adapted the more-complex configuration of mixing/agitating means of O'Connor in the process of Saim et al, to effect greater, more complete mixing of components which are in slurry form, or mixing of materials of different phases (liquids, solids, semi-solids and gases). The Examiner further states Johnson et al teach production of nanoparticles using supercritical fluid processing in which the inlet tubes are within 15% of the agitator surface diameter (see especially paragraph 44, paragraphs 39-42, 58 and 63), and that it would have been obvious to one of ordinary skill in the art to have

located the end of the inlet tubes of Saim et al very close to the impeller agitators as suggested by Johnson et al, to facilitate rapid incorporation of the incoming fluid into the swept region of the agitator and rapid mixing.

Contrary to the Examiner's assertions, it would not have been obvious to combine the individual teachings of Saim et al, O'Connor and Johnson et al in the manner alleged in order to arrive at the present claimed invention, as each of such references employ distinct types or materials and or apparatuses for distinct purposes. Saim et al, e.g., is directed towards coating or dispersion of precipitated particles in a fluidized bed of powder carrier material. While a rotary agitator is disclosed for agitation of the fluidized bed, Saim does not teach that both a first feed stream including particle-forming components and solvent and a second feed stream containing supercritical fluid should be introduced proximate an agitated/highly agitated zone of the mixer. In such connection, the Examiner's reliance upon column 12, lines 11-12 taken with lines 33-36 of column 12 is clearly in error, as lines 11-12 are directed towards a first "Mode 1" employing RESS techniques (and thus there are not separate first and second streams introduced into the vessel, but rather only a single pressurized stream which is expanded upon entry into the vessel), while lines 33-36, which are directed towards a SAS type process more similar to the present process, do not teach entry of the separate solutions and pressurized gaseous fluid in a highly agitated zone within one impeller diameter of the agitator impeller surface. To the contrary, Saim discloses a preference for the introduction of the pressurized gaseous fluid only from above an upper surface of the bed of carrier particles, and of the organic liquid solution from a level below or slightly above the upper surface of the bed of carrier particles (col. 13, lines 24-28), and mixing of the bed of carrier particles to coat the carrier particles with particles of material precipitated from the solution. As Saim is clearly directed toward obtaining a specific result different from that of O'Connor and Johnson et al. (i.e., coating of particles in a fluidized particulate bed), it would not be "obvious" to change such process away from the specifically described preferences based on references which are not directed towards achieving such result.

It is further noted that the O'Connor process, although employing different mixing impellers and supercritical fluids, is directed towards the size reduction of pre-made macro particles, rather than the direct precipitation of

smaller sized particles. The physics of size reduction is fundamentally different from that of particle formation via precipitation, and no reasonable extrapolation can be made from the proposed combination of the Saim et al process with the teachings of O'Connor.

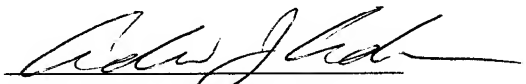
Regarding Johnson et al, the referenced teaching in paragraph [0044] thereof of employing inlet tubes which are within 15% of an agitator surface diameter (in order to facilitate rapid incorporation of the incoming fluid into the swept region of the agitator and rapid mixing) is essentially duplicative of the already acknowledged prior art mixing technology discussed at page 9, lines 24-31 and the paragraph bridging pages 10-11 of the specification. What is not taught or suggested, by either Johnson et al or the acknowledged prior art mixing technology, is to employ such type known type of mixing technology apparatus in a SAS type particle formation process. To the contrary, Johnson et al is directed towards making of nanoparticles of amphiphilic copolymers in conventional solvents. Further, while Johnson et al discloses the use of liquefied gas such as carbon dioxide as a non-process solvent (paragraph [0058]), and that the formed amphiphilic copolymer nanoparticles can be subsequently altered a supercritical fluid extraction post treatment process (paragraph [0063]), there does not appear to be any support for the Examiner's assertion that Johnson et al teach production of nanoparticles using supercritical fluid processing. To the contrary, Johnson et al does not teach the use of supercritical fluid as is required for practicing the present claimed invention. The process of Johnson et al does not enable production of particles having a volume-weighted average diameter of below 20 nm as required by claim 1.

Johnson et al actually teaches that an agitator is not even required in the disclosed process if the fluids added into a non-solvent have a high mixing velocity sufficient to mix the fluid contents rapidly and in a controlled fashion (see, e.g., last 4 lines of paragraph [0017]). Supercritical fluids as required in the present invention are known to have gas-like transport properties, as noted at page 1, line 10 of the specification. For micromixing, the critical transport property of interest is molecular diffusivity. Gas-like molecular diffusivity lowers mixing time to levels not attainable in liquids. Thus, Johnson et al in fact would appear to teach that a mixer would not be required for mixing in supercritical fluids, thus teaching away from the present invention.

Finally, while it is believed that a prima facie case of obviousness has not been established based on the arguments above, it is further noted that any such alleged prima facie case of obvious is in any event overcome by the surprising results of the present invention. As disclosed in Examples 4-8 of the present application, the invention enables production of particles less than 20 nm in diameter for a number of materials, many of them substantially smaller than even 10 nm, while none of the cited references teach a process which enables such small particle size. Reconsideration of this rejection is accordingly respectfully requested.

In view of the foregoing amendments and remarks, reconsideration of this patent application is respectfully requested. A prompt and favorable action by the Examiner is earnestly solicited. Should the Examiner believe any remaining issues may be resolved via a telephone interview, the Examiner is encouraged to contact Applicants' representative at the number below to discuss such issues.

Respectfully submitted,



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